 DEC 30 2013

# 510(k) SUMMARY: MONUMENT™ Spacer

**Company:** Globus Medical Inc.
2560 General Armistead Avenue.
Audubon, PA 19403
(610) 930-1800

**Contact:** Christina Kichula
Group Manager, Regulatory Affairs

**Date Prepared:** August 14, 2013

**Device Name:** MONUMENT™ Spacers

**Classification:** Per 21 CFR as follows:
§888.3080 Intervertebral Body Fusion Device
Product Code: OVD
Regulatory Class: II, Panel Code: 87

**Predicate(s):** Globus Medical INDEPENDENCE® Spacer (K082252 & K120101)

**Purpose:**
The purpose of this submission is to request clearance for MONUMENT™ Spacers.

**Device Description:**
The MONUMENT™ Spacer is an anterior lumbar interbody fusion device used to provide structural stability in skeletally mature individuals following discectomy. The MONUMENT™ Spacer is intended to aid in reduction of a Grade 1 spondylolisthesis. The spacer is available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to aid in expulsion resistance. Screws are inserted through the anterior titanium portion of the implant into adjacent vertebral bodies for bony fixation. The spacer is to be filled with autogenous bone graft material.

The MONUMENT™ Spacer is made from radiolucent PEEK polymer and titanium alloy, as specified in ASTM F136, F1295, and F2026. The mating screws are manufactured from titanium alloy, as specified in ASTM F136 and F1295, and are available with hydroxyapatite (HA) coating, as specified in ASTM F1185.

**Indications for Use:**
The MONUMENT™ Spacer is an interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These

patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The MONUMENT™ Spacer is to be filled with autogenous bone graft material, and is to be used with four titanium alloy screws that accompany the implant. The device is intended to be used with supplemental fixation (i.e. pedicle screws, facet fixation).

**Performance Data:**
Mechanical testing (static and dynamic compression, static and dynamic compression shear, subsidence, and expulsion) was conducted in accordance with the "Guidance for Industry and FDA Staff, Class II Special Controls Guidance Document: Intervertebral Fusion Device," June 12, 2007, ASTM F2077, and ASTM 2267. Performance and comparative analysis data demonstrate that the different technological features do not affect the safety and effectiveness of the device and support substantial equivalence to the predicate devices.

**Basis for Substantial Equivalence:**
MONUMENT™ Spacers have been found to be substantially equivalent to the predicate with respect to technical characteristics, performance, design, materials, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate device. MONUMENT™ Spacers are as safe, as effective, and perform as well as or better than predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 30, 2013

Globus Medical, Incorporated
Ms. Christina Kichula
Group Manager, Regulatory Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K132559
Trade/Device Name: MONUMENT™ Spacers
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: December 4, 2013
Received: December 5, 2013

Dear Ms. Kichula:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number: K132559

Device Name: MONUMENT™ Spacers

**INDICATIONS:**

The MONUMENT™ Spacer is an interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The MONUMENT™ Spacer is to be filled with autogenous bone graft material, and is to be used with four titanium alloy screws that accompany the implant. The device is intended to be used with supplemental fixation (i.e. pedicle screws, facet fixation).

Prescription Use ___X___ OR Over-The-Counter Use___
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Hwang, Ph.D.
Division of Orthopedic Devices